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Dated: August 4, 2003

Signature:

Stacy Harris
(Stacy V. Harris)

Docket No.: H01-P01938US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Morten Soegaard, et al.

Application No.: 09/463,470

Group Art Unit: 1644

Filed: January 21, 2000

Examiner: Sanders, David

For: CYTOLYSIS OF TARGET CELLS BY
SUPERANTIGEN CONJUGATES INDUCING
T-CELL ACTIVATION

Assistant Commissioner for Patents
Alexandria, VA 22313

RULE 1.132 DECLARATION

Dear Sir:

I, the undersigned Morten Soegaard, Lars Abrahmsen, Peter Lando, Göran Forsberg, Terje Kalland, Mikael Dohlsten, or Hans Belfrage, hereby declare and state the following, with the understanding that all statements made here of my own knowledge are true and all statements made on information and belief are believed to be true:

1. Morten Soegaard, Lars Abrahmsen, Peter Lando, Göran Forsberg, Terje Kalland, and Mikael Dohlsten are the co-inventors of subject matter claimed in the above-referenced patent application, which subject matter relates to combinations of superantigens and immune modulators, wherein at least one of the superantigen or immune modulator is conjugated to a targeting moiety, and the use of these combinations.

2. Hans Belfrage is not a co-inventor of subject matter claimed in the above-referenced patent application, which subject matter relates to combinations of superantigens and immune modulators, wherein at least one of the superantigen or immune modulator is conjugated to a targeting moiety, and the use of these combinations.

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3. A Doctoral Thesis by Hans Belfrage, entitled "Activation of Murine Cytotoxic Cells with Interleukin-2 and the Bacterial Superantigen Staphylococcal Enterotoxin A," published September 27, 1996, by the University of Lund, Lund Sweden (hereafter referred to as the "Belfrage Thesis"), has been cited by the U.S. Patent and Trademark Office against the above-referenced patent as prior art which allegedly discloses or suggests the invention claimed in the patent application.

4. The subject matter of the Belfrage Thesis relates to combinations of superantigens and immune modulators, and the use of these combinations, wherein neither the superantigen nor the immune modulator is conjugated (i.e., the subject matter of the Belfrage Thesis relates to the use of free, unconjugated superantigens and free, unconjugated immune modulators).

5. While the subject matter of the Belfrage Thesis, including all examples and data, relates to free, unconjugated superantigens and free, unconjugated immune modulators, there are some statements in the discussion sections of the Belfrage Thesis which suggest that the work of Belfrage could be applied to the use of conjugated, targeted superantigens. For example, the Belfrage Thesis states: "It is tempting to suggest that combined administration of IL-2 [an immune modulator] and SEA [a superantigen] will be useful in the recently described use of antibody targeted superantigens for tumor therapy ([citing Dohlsten *et al.*, *Proc. Natl. Acad. Sci. USA* 88, 9287 (1994), and Dohlsten *et al.*, *Proc. Natl. Acad. Sci. USA* 91, 8945 (1994)])."

6. To the extent that such statements may disclose or suggest the claimed invention of the above-referenced patent application, such statements reflected solely the ideas of the co-inventors of the above-referenced patent application and not the ideas of Hans Belfrage. Hans Belfrage had a close working relationship with, and was under the training and supervision of, among other co-inventors, Terje Kalland and Mikael Dohlsten. Terje Kalland was Hans Belfrage's thesis advisor and is thanked and acknowledged in the Belfrage Thesis as Belfrage's "mentor and supervisor." Mikael Dohlsten is thanked and acknowledged in the Belfrage Thesis "for his enormous enthusiasm and the last years stand in as my mentor when needed." Therefore, to the extent any statements in the Belfrage Thesis may disclose or suggest the claimed invention of the above-referenced patent application, they reflect the ideas of the co-inventors.

7. I declare that all statements made here of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: July 24, 2003


Morten Soegaard

Date: _____

Lars Abrahmsen

Date: _____

Peter Lando

Date: _____

Göran Forsberg

Date: _____

Terje Kalland

Date: _____

Mikael Dohlsten

Date: _____

Hans Belfrage

7. I declare that all statements made here of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____

Date: July 24, 2003

Date: _____

Date: _____

Date: _____

Date: _____

Date: _____

Morten Soogaard

Lars Hv

Lars Abrahamsen

Peter Lando

Göran Forsberg

Terje Kalland

Mikael Dohlisten

Hans Belfrage

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7. I declare that all statements made here of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

Date: _____

Morten Soegaard

Date: _____

Lars Abrahmsen

Date: 22 July 2003

Peter Lando

Peter Lando

Date: _____

Göran Forsberg

Date: _____

Terje Kalland

Date: _____

Mikael Dohlsten

Date: _____

Hans Belfrage

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Date: _____

Morten Soegaard

Date: _____

Lars Abrahamsen

Date: _____

Peter Lando

Date: July 3


Gøran Forsberg

Date: _____

Terje Kalland

Date: _____

Mikael Dohlsten

Date: _____

Hans Belfrage

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7. I declare that all statements made here of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____

Morten Soegaard

Date: _____

Lars Abrahamsen

Date: _____

Peter Lando

Date: _____

Göran Forsberg

Date: 4/7/03

O. Kalland

Torje Kalland

Date: _____

Mikael Dohlsten

Date: _____

Hans Belfrage

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7. I declare that all statements made here of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____

Morten Soegaard

Date: _____

Lars Abrahmsen

Date: _____

Peter Lando

Date: _____

Göran Forsberg

Date: _____

Terje Kalland

Date: 3/7-2003

Mikael Dohlsen

Mikael Dohlsen

Date: _____

Hans Belfrage

7. I declare that all statements made here of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____

Morten Soegaard

Date: _____

Lars Abrahmsen

Date: _____

Peter Lando

Date: _____

Göran Forsberg

Date: _____

Terje Kalland

Date: _____

Mikael Dohlsten

Date: 030702


Hans Belfrage

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Examiner: Sindurs, David

For: CYTOLYSIS OF TARGET CELLS BY
SUPERANTIGEN CONJUGATES INDUCING
T-CELL ACTIVATION

Assistant Commissioner for Patents
Washington, D.C. 20231

1.132 DECLARATION

Dear Sir:

The undersigned, Terje Kalland, M.D., Ph.D., hereby declares and states that:

1. I am a co-inventor of subject matter claimed in the above-referenced patent application.
2. I have read the above-referenced application, and I have read the pertinent Office Action.
3. My current position is a Chief Scientific Officer at Biotechnology, Lindhagensgatan 133, Stockholm, Sweden.
4. The subject matter contained in the reference, Belfrage et al., *Immunology* (February) 90:183-188, 1997 was material derived and published by myself and the other inventor, Mikael Dohlsten, the other authors were merely working under the direction of myself and Mikael Dohlsten.
5. The subject matter contained in the reference, Lando et al., *J. Immunology* (October) 157:2857-2863, 1996 was material derived and published by myself and the other inventors, Mikael Dohlsten and Peter Lando, the other authors

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were merely working under the direction of myself, Mikael Dohlsten and Peter Lando.

6. I, Terje Kalland, assert that the inventorship of the above referenced application is correct and I assert that claims 35-46, as made by Terje Kalland, Mikael Dohlsten, Morten Soegaard, Lars Abrahmsen, Goran Forsberg, and Peter Lando, were conceived by the Applicants and in-part published in the Belfrage et al. and Lando et al. reference.

7. I declare that all statements made here of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

Date: August 7, 2003



Terje Kalland, M.D., Ph.D.

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